

## **REMARKS**

### **1. Amendments to the Claims**

Claims 1 and 20 have been amended to recite “even if not using any coating or microcapsulation technique” to result in a medicament-containing particle wherein said medicament is overall uncoated or not microcapsulated. Support for these amendments is found in the Specification at page 21, lines 6-8.

No new matter has been added.

### **2. Claim Rejections**

#### **a. Obviousness**

#### ***Siebert***

The Examiner rejects claims 22-23 under 35 U.S.C. § 103 as unpatentable over Siebert et al. Applicants respectfully traverse.

The Examiner rejects claims 1, 4-7, 11, and 13-20 under 35 U.S.C. §103 as unpatentable over Siebert et al. The Examiner first indicates that since the “particles” in the specification, at page 21, can contain additional excipients and is a solid form, it is viewed as the same as a granule or powder with the same components which are taught by Siebert. (Office Action, page 5). Applicants respectfully disagree.

- i. Siebert does not teach the particle structure of the invention.

Siebert teaches granules or powders, both of which are “coated” for taste masking purposes and for extended release. (See col. 2, lines 13-16 and col. 4, lines 50-53). In a tablet according to Siebert, the coated particle is mixed with mannitol (the filler, col. 6, lines 46-55) and

microcrystalline cellulose (Avicel, the binder, col. 7, lines 7-10, and 18-20), among other ingredients. The binder can alternately be methyl cellulose, col. 7, lines 31-33.

It is generally well-known that the coating of a medicament having an unpleasant taste makes the unpleasant taste alleviated. In the present invention, however, the medicament in the medicament-containing particle is not overall coated, because the present invention has a characteristic of masking an unpleasant taste even if not any coating. (Specification, page 21, lines 7-8).

Based on the teachings of Siebert at column 10, line 42-43, one of skill would expect that a coating would be required to mask the unpleasant taste of the medicament. Thus, one of skill would have no reasonable expectation that an uncoated particle as in the present invention would not cause an unpleasant taste. Accordingly, the Examiner has failed to establish a *prima facie* case of obviousness.

Additionally, Applicants present the Declaration of Dr. Shimono, showing that masking taste by coating the medicament particles is very different from the present invention (Declaration, page 2, paragraph 7). Applicants submit that the evidence of the Shimono Declaration shows that the compositions of the present invention are unexpectedly effective at masking an unpleasant taste. Thus, Applicants submit that one of skill would not have found the present invention obvious.

- ii. One of skill would not substitute methylcellulose for microcrystalline cellulose.

Moreover, the substitution of methyl cellulose for microcrystalline cellulose as a binder does not suggest to one of skill that the addition of methylcellulose in a *particle* containing a medicament would mask the unpleasant taste of the medicament. (See, Declaration, page 2, paragraph 8.) This is supported by the comparative results shown in the Declaration, where microcrystalline cellulose was substituted for methylcellulose in the particles and did not mask the unpleasant taste of the medicament. (See, Declaration, beginning at page 3, paragraphs 9-11).

Thus, even if one of skill spontaneously applied the teachings of Siebert to make a particle including a binder (without any disclosed reason to do so) the particle would not have the effects of the present invention. Accordingly, Applicants submit that one of skill in the art would not have found the present invention obvious from the teachings of Siebert.

- iii. Taste is a characteristic of the compositions in Siebert and in the present invention; and the lack of an unpleasant taste is unexpected.

The Examiner also states that “[t]he recitation of intended use for taste does not have patentable weight in a composition claim.” (Office Action, page 5). Applicants submit that the lack of an unpleasant taste is a characteristic of the composition, not an “intended use.” Even if the Examiner finds that the taste is not a characteristic of the claimed composition, the Examiner is required to give it patentable weight.

The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim. *Corning Glass Works*, 868 F.2d at 1257, 9 USPQ2d at 1966. [C]lear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention. *Catalina Mktg. Int'l v. Coolsavings.com, Inc.*, 289 F.3d at 808-09, 62 USPQ2d at 1785.

(MPEP 2111.02 (II)) (internal quotations omitted).

Moreover, the unexpected masking effects apply across to multiple unpleasant tasting medicaments. The Specification at Example 1 shows that the particles alone completely masked the unpleasant taste of mosapride. See Specification, page 29 table 1, and page 44, table 18. The Shimono Declaration shows that this effect is present over at least eight different unpleasant tasting medicaments. (Declaration, page 6, Table 5). This result further supports the unexpected results of the claimed invention.

***Siebert, Depui, and Yoshinari (and Shirai)***

The Examiner rejects claims 8-10, 18, and 21 as unpatentable over Siebert et al. in view of Depui et al., (U.S. Pat. No. 6368625) and Yoshinari et al. (US. Pat. No. 6235947) (and Shirai U.S. Patent 6,413,541). Applicants respectfully traverse.

The Examiner suggests that Applicants have approached the references individually. However, Applicants note that the deficiencies in the references are primarily found in the Siebert reference. Because Applicants have already addressed the Siebert reference, it is appropriate that if the elements found lacking in the primary reference are not supplied by the secondary references, it is sufficient to indicate that a prima facie case of obviousness has not been established without reaching the arguable merits of whether the references do teach any other aspects the Examiner suggests they teach. A feature missing from the entire collection of references cited is not going to suddenly appear in some combination of them.

However, in order to address the Examiner's concerns, Applicants submit that Siebert does not teach the following:

- the medicament-containing particles (*i.e.*, the lack of coating)<sup>1</sup>
- a composition containing both medicament-containing particles and the additional substances
- methylcellulose in a granule form (Office Action, page 3)

The combination of Siebert, Depui (cited for mosapride), Yoshinari (cited for D-mannitol), Shirai (cited for packaging) does not provide the medicament-containing particles of the

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<sup>1</sup> The Examiner in the Office Action at page 3 states: "Example 1 [of Siebert] is a powder (granular) composition comprising famotidine, microcrystalline cellulose (Avicel), and crospovidone that is formed into a tablet." The Examiner mischaracterizes the teachings of Siebert because a coated powder is formed of Famotidine, Surelease (Ethyl cellulose), water, and Opadry (hydroxypropyl methyl cellulose). (Siebert, Example 1, col. 11, lines 15-31). The *tablets* are formed from the mixture of the powder and additional ingredients, including mannitol. (Siebert, Example 1, col. 11, lines 40-45).

invention. Thus, for the reasons discussed above, the rejection fails to establish a prima facie case of obviousness. Moreover, none of the references address the unexpected result of masking an unpleasant taste. Thus, Applicants submit that any alleged prima facie obviousness is overcome by the unexpected results shown in the Specification and in the Shimono Declaration. Applicants respectfully request that the rejection be withdrawn.


Applicants submit that the present application claims subject matter free of the prior art. The favorable actions of withdrawal of the standing rejections and allowance of the pending claims are requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell Reg. No. 36,623, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §§1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

By   
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Attachments: Shimono Declaration